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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/701,062	11/05/2003	Amir Mikel Rahbar	108172-00103	6293
4372	7590	11/02/2005	EXAMINER	
ARENT FOX PLLC 1050 CONNECTICUT AVENUE, N.W. SUITE 400 WASHINGTON, DC 20036				MILLER, MARINA I
ART UNIT		PAPER NUMBER		
		1631		

DATE MAILED: 11/02/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	10/701,062	RAHBAR ET AL.
	<b>Examiner</b> Marina Miller	<b>Art Unit</b> 1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

1)  Responsive to communication(s) filed on 14 October 2003.

2a)  This action is **FINAL**.                            2b)  This action is non-final.

3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## **Disposition of Claims**

4)  Claim(s) 1-15 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
5)  Claim(s) \_\_\_\_\_ is/are allowed.  
6)  Claim(s) 1-15 is/are rejected.  
7)  Claim(s) \_\_\_\_\_ is/are objected to.  
8)  Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

9)  The specification is objected to by the Examiner.

10)  The drawing(s) filed on 05 November 2003 is/are: a)  accepted or b)  objected to by the Examiner.

    Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

    Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)  The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a)  All b)  Some \* c)  None of:  
1.  Certified copies of the priority documents have been received.  
2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1)  Notice of References Cited (PTO-892)  
2)  Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3)  Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_

4)  Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_  
5)  Notice of Informal Patent Application (PTO-152)  
6)  Other: \_\_\_\_\_

## **DETAILED ACTION**

Applicants' submission filed on 10/14/2003 is acknowledged. Claims 1-15 are pending.

Claims 1-15 presently are under examination.

### ***Priority***

Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date, the U.S. provisional application 60/424,054 filed 11/05/2002. Claims 1-15 are drawn to a method of separating plasma membranes comprising steps of isolating plasma membranes, washing the membranes, solubilizing the silica coated plasma membranes, separating the plasma proteins, digesting the proteins, analyzing the proteins by mass spectrometry, and searching a bioinformatics database. The steps of washing, solubilizing, separating plasma membrane proteins are not supported by the priority application. Also, the combination of steps recited in instant claims 1-15 is not supported in the provisional application 60/424,054.

If applicant desires benefit of this provisional application, applicant is invited to point to specific support by page and line number for each limitation of instant claims in the provisional application mentioned above. Priority for claims 1-15 is granted only to the filing date of the instant application filed 11/05/2003.

### ***Specification***

### ***Abstract***

The abstract is objected to because it does not properly describe the claimed invention, which is directed to a process. Applicants are required to submit a new abstract reflecting what is the essence of the claimed invention and set forth a process of the invention.

***Claim Objection***

Claims 12 and 14 are objected to under 37 CFR 1.75 as being a substantial duplication of claims 8 and 10, respectively. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Appropriate correction is required.

***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-15 are rejected under 35 U.S.C. 101 because the claimed invention lacks patentable utility.

A method of claim 1 is directed to a method of separating plasma membranes comprising steps of isolating plasma membranes, washing the membranes, solubilizing the silica coated plasma membranes, and separating the plasma proteins. Claims 2, 4, 9, and 13 further comprise steps of excising and digesting the proteins, and analyzing the proteins by mass spectrometry and searching a bioinformatics database. The specification on p. 1 discloses that information obtained about plasma membrane proteins helps to facilitate the drug discovery process. However the disclosed utility is not applicable to the instant claims. For example, the result of the method of claim 1 is a set of separated plasma membrane proteins on a gel. The result of claims 2, 4, 9, and 13 is an analysis of the proteins with MS and a search of bioinformatics database. A method of

separating plasma membranes/proteins MAY have a “substantial” utility, if one knew parameters and/or purpose of the membrane proteins separation and/or purpose and/or parameters of analyzing by MS and criteria of searching a database. However, the specification does not disclose any specific utility for the invention because the claims do not recite a drug target, a protein function, what trait, disease, or phenotype is being analyzed, and/or a purpose and criteria of searching a bioinformatics database. In order for the result of the method to be used for the drug discovery process, one skilled in the art must be aware of the correlation between the information received and a condition to be treated. Absent any disclosure about proteins, their functions, and/or pathways, a goal of MS and bioinformatics analysis and purpose/criteria of a database searching, and/or a correlation between information “received” and a disease to be treated, the asserted utility is not specific. No such information is recited in the instant claims. Applicant is reminded that a “use” to perform further research is not a utility under 35 U.S.C. 101. For the reasons set forth above, the invention lacks a specific utility, and therefore lacks a patentable utility.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is directed to a method comprising a step of isolating plasma membranes with a “plasma membrane isolation step.” It is not clear whether an isolating step comprises another

isolation step, or is conducted by using a cationic colloidal silica membrane, or the isolating step is a cationic colloidal silica plasma membrane isolating step. As the intended limitation is not clear, claim 1 is indefinite. Claim 2 depends from claim, and therefore is indefinite.

Claim 1 recites in the preamble "a method of separating plasma membranes." None of the steps is actually directed to separating plasma membranes. The result of the method is separating the plasma membrane proteins. It is not clear if the preamble is intended to limit the method and what relationship is intended between the preamble and the method steps. Thus, claims 1-2 are indefinite.

Claims 1, 8, and 12 recite the limitation "prior to any proteolytic digestion." However, none of the method steps is actually directed to proteolytic digestion. It is not clear whether the limitation "prior proteolytic digestion" is intended to limit the claim. As the intended limitation is not clear, claims 1-2 are indefinite.

Claims 1 and 3 recite the limitation "the plasma membrane proteins." There is insufficient antecedent basis for this limitation in the claim. Thus, claims 1 and 3 are indefinite. Claims 4-15 depend from claim 3 and claim 2 depend from claim 1. Thus, claims 1-15 are indefinite.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 3, 5, 7-8, 10, 12, and 14 rejected under 35 U.S.C. 102(b) as being anticipated by Schnitzer, U.S. Patent 6,255,457.

Schnitzer discloses a method for isolating membrane proteins (*see* a general description col. 3-4) comprising isolating plasma membranes with colloidal silica particles (col. 13, line 30-55; col. 15, line 15-35), washing the isolated membranes with sodium carbonate to produce silica coated plasma membrane (col. 13, line 30-55), solubilizing the silica coated membranes (col. 14, line 45-55; col. 15, line 48-60; col. 18, line 50-67), and separating the membrane proteins (col. 14, line 43-56; col. 15, line 54-60). Thus, Schnitzer anticipates claim 3. Schnitzer discloses washing with sodium carbonate (col. 13, line 30-55), thus anticipating claim 5. Schnitzer discloses a separation of membrane proteins with a cationic colloidal plasma membrane (fig. 1-2, col. 3, line 11-64), thus anticipating claim 7. Schnitzer discloses solubilizing the silica coated membranes (col. 14, line 45-55; col. 15, line 48-60; col. 18, line 50-67), thus anticipating claims 8 and 12. Schnitzer discloses washing with sodium carbonate (col. 13, line 29-55), thus anticipating claims 10 and 14.

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 4, 9, and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schnitzer, U.S. Patent 6,255,457, as applied to claims 3, 5, 7-8, 10, 12, and 14 above, in view of Seshi, US 2003/0203483.

Claims 4, 9, and 13 further comprise excising and digesting the proteins, and analyzing the proteins by mass spectrometry and searching a bioinformatics database.

Schnitzer teaches a method of claims 3, 5, 7-8, 10, 12, and 14, as set forth above.

Schnitzer does not teach excising and digesting the proteins, and analyzing the proteins by mass spectrometry and searching a bioinformatics database.

Seshi discloses a method of isolating membrane-bound proteins comprising separating proteins by SDS/PAGE gel, digesting proteins [0238], analyzing by MS, and searching a database for identifying the membrane proteins (see [0098], [0216], [0238-[0240]]).

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to modify the method of Schnitzer to use MS analysis and a bioinformatics database search, such as taught by Seshi, where the motivation would have been to identify plasma membrane proteins for a therapeutic and diagnostic purpose, as taught by Seshi, [0020] and [0098] at page 10.

Claims 1, 6, 11, and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schnitzer, U.S. Patent 6,255,457, as applied to claims 3, 5, 7-8, 10, 12, and 14 above, in view of Emery, U.S. Patent 5,830,479.

Schnitzer teaches a method of claims 3, 5, 7-8, 10, 12, and 14, as set forth above.

Although Schnitzer discloses solubilizing with SDS (col. 15, line 53-54; col. 18, line 66), he does not specifically disclose solubilizing with 2% SDS.

Emery discloses a method of purification of membrane proteins comprising solubilizing with 2% SDS (col. 10, line 51-64).

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to modify the method of Schnitzer to solubilize membrane proteins with 2% SDS, such as taught by Emery, where the motivation would have been to improve efficiency of extracting membrane proteins, as taught by Emery, col. 10, line 55-62.

Claims 1 and 2 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schnitzer, U.S. Patent 6,255,457, in view of Seshi, US 2003/0203483, as applied to claims 3-5, 7-10, and 12-14 above, and further in view of Emery, U.S. Patent 5,830,479.

Schnitzer and Seshi teach and make obvious a method of claims 3-5, 7-10, and 12-14, as set forth above.

Although Schnitzer discloses solubilizing with SDS (col. 15, line 53-54; col. 18, line 66), Schnitzer and Seshi do not specifically disclose solubilizing with 2% SDS.

Emery discloses a method of purification of membrane proteins comprising solubilizing with 2% SDS (col. 10, line 51-64).

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to modify the method of Schnitzer and Seshi to solubilize membrane proteins with 2% SDS, such as taught by Emery, where the motivation would have been to improve efficiency of extracting membrane proteins, as taught by Emery, col. 10, line 55-62.

***Conclusion***

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marina Miller whose telephone number is (571)272-6101. The examiner can normally be reached on 8-5, M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, Ph. D. can be reached on (571)272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Marina Miller  
Examiner  
Art Unit 1631

MM

MARJORIE A. MORAN  
PRIMARY EXAMINER

*Marjorie A. Moran*  
9/28/05